

Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Federal Crop Insurance Corporation

7 CFR Part 457

Common Crop Insurance Regulations; Guaranteed Production Plan of Fresh Market Tomato Crop Insurance Provisions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) proposes to amend the Guaranteed Production Plan of Fresh Market Tomato Crop Insurance Provisions to change the calendar date for the end of the insurance period.

DATES: Written comments and opinions on this proposed rule will be accepted until close of business August 19, 1998 and will be considered when the rule is to be made final.

ADDRESSES: Interested persons are invited to submit written comments to the Director, Product Development Division, Federal Crop Insurance Corporation, United States Department of Agriculture, 9435 Holmes Road, Kansas City, MO 64131. A copy of each response will be available for public inspection and copying from 7:00 a.m. to 4:30 p.m., CDT, Monday through Friday, except holidays, at the above address.

FOR FURTHER INFORMATION CONTACT: Louise Narber, Insurance Management Specialist, Research and Development, Product Development Division, Federal Crop Insurance Corporation, at the Kansas City, MO, address listed above, telephone (816) 926-7730.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined to be exempt for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget (OMB).

Paperwork Reduction Act of 1995

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 35) there are no information collection requirements contained in this rule.

Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform of 1995 (UMRA) establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local, and tribal governments and the private sector. This rule contains no Federal mandates (under the regulatory provisions of title II of UMRA) for State, local, and tribal governments or the private sector. Therefore, this rule is not subject to the requirements of sections 202 and 205 of UMRA.

Executive Order 12612

It has been determined under section 6(a) of Executive Order No. 12612, Federalism, that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment. The provisions contained in this rule will not have a substantial direct effect on States or their political subdivisions or on the distribution of power and responsibilities among the various levels of government.

Regulatory Flexibility Act

This regulation will not have a significant economic impact on a substantial number of small entities. New provisions included in this rule will not impact small entities to a greater extent than large entities. The amount of work required of the insurance companies delivering and servicing these policies will not increase from the amount of work currently required. Therefore, this action is determined to be exempt from the provisions of the Regulatory Flexibility Act (5 U.S.C. 605) and no Regulatory Flexibility Analysis was prepared.

Federal Assistance Program

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

Executive Order 12372

This program is not subject to the provisions of Executive Order 12372 which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR

part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

Executive Order 12988

This proposed rule has been reviewed in accordance with Executive Order 12988 on civil justice reform. The provisions of this rule will not have a retroactive effect. The provisions of this rule will preempt State and local laws to the extent such State and local laws are inconsistent herewith. The administrative appeal provisions published at 7 CFR part 11 must be exhausted before any action for judicial review of any determination made by FCIC may be brought.

Environmental Evaluation

This action is not expected to have a significant economic impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

Background

FCIC proposes to amend the Common Crop Insurance Regulations (7 CFR part 457) by revising 7 CFR 457.128 effective for the 1999 and succeeding crop years. The only change to the provisions for insuring guaranteed production plan of fresh market tomatoes is to amend section 10(b)(7) to change the calendar date for the end of the insurance period for certain states. The end of the insurance period for Delaware, Maryland, New Jersey, North Carolina, and Virginia will be changed from September 20 to October 15 of the crop year. The end of the insurance period for Florida, Georgia, and South Carolina will be changed from September 20 to November 10 of the crop year. A September 20 ending date creates an insurance period that is too short in these states. Under the current crop provisions, if the crop is planted during the fall planting period in accordance with the Special Provisions in effect for the 1999 crop year, the crop will not reach maturity before the end of the insurance period. The proposed change in the dates for the end of the insurance period will allow for insurance coverage from the time of planting until maturity of the crop.

List of Subjects in 7 CFR Part 457

Crop insurance, Tomatoes.

Proposed Rule

Accordingly, as set forth in the preamble, the Federal Crop Insurance Corporation, proposes to amend 7 CFR part 457 as follows:

PART 457—COMMON CROP INSURANCE REGULATIONS; REGULATIONS FOR THE 1998 AND SUBSEQUENT CONTRACT YEARS

1. The authority citation for 7 CFR part 457 continues to read as follows:

Authority: 7 U.S.C. 1506(l), 1506(p).

2. In § 457.128 revise section 10(b)(7) to read as follows:

§ 457.128 Guaranteed Production Plan of Fresh Market Tomato Crop Insurance Provisions.

10. Insurance Period.

* * * * *

(b) * * *

(7) October 15 of the crop year in Delaware, Maryland, New Jersey, North Carolina, and Virginia; October 31 of the crop year in California; November 10 of the crop year in Florida, Georgia, and South Carolina; and September 20 of the crop year in all other states.

Signed in Washington, DC, on July 13, 1998.

Kenneth D. Ackerman,

Manager, Federal Crop Insurance Corporation.

[FR Doc. 98-19245 Filed 7-17-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 341

[Docket No. 76N-052T]

RIN 0910-AA01

Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products for Over-the-Counter Human Use; Proposed Amendment of Final Monograph for OTC Antitussive Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking that would amend the final monograph for over-the-counter (OTC) antitussive drug products (drug products that relieve cough) to revise the labeling warnings and directions for topical/inhalant products containing the active ingredients

camphor and/or menthol. New information indicates that use of these drug products near an open flame, in hot water, or in a microwave oven can cause the products to catch on fire and cause serious burns to the user. Therefore, the agency is proposing warnings and directions for safer use of these drug products by informing consumers not to expose the products to flame, hot water, or a microwave oven. This proposal is part of the ongoing review of OTC drug products conducted by FDA.

DATES: Submit written comments by October 19, 1998; written comments on the agency's economic impact determination by October 19, 1998. FDA is proposing that any final rule that may issue based on this proposal become effective 12 months after its date of publication in the **Federal Register**.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Elizabeth A. Ryland, Center for Drug Evaluation and Research (HFD-560), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2222.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of September 9, 1976 (41 FR 38312 at 38343), the Advisory Review Panel on OTC Cold, Cough, Allergy, Bronchodilator, and Antiasthmatic Drug Products (the Panel) recommended that the single ingredients camphor and menthol for topical/inhalant antitussive use be classified in Category III (available data are insufficient to classify as safe and effective, and further testing is required). The Panel based its recommendations on a lack of effectiveness data, but determined that these products are safe (41 FR 38312 at 38344 and 38349 to 38352). The Panel was not aware of and did not discuss any information concerning possible safety hazards occurring when these products are placed near a flame, into containers of hot water, or in a microwave oven. The Panel recommended the following directions for topical/inhalant use for camphor and menthol:

* * * 1 tablespoonful of solution per quart of water is added directly to the water in a hot steam vaporizer, bowl, or washbasin; or 2 teaspoonfuls of solution per pint of water are added to an open container of boiling water. Breathe in vapors during the period of medicated steam generation. May be repeated 3 times daily.

In the final monograph for OTC antitussive drug products (52 FR 30042 at 30045 to 30046, August 12, 1987), the agency provided the following directions in § 341.74(d)(2)(i) and (d)(2)(ii) (21 CFR 341.74(d)(2)(i) and (d)(2)(ii)) for products containing the single ingredient camphor or menthol for ointment vehicle use based on additional clinical studies that supported effectiveness:

* * * Adults and children 2 to under 12 years of age: Rub on the throat and chest as a thick layer. The area of application may be covered with a warm, dry cloth if desired. However, clothing should be left loose about the throat and chest to help the vapors rise to reach the nose and mouth. Applications may be repeated up to three times daily or as directed by a doctor. Children under 2 years of age: consult a doctor.

For products containing the single ingredient camphor or menthol for steam inhalation use, the agency provided the following directions in § 341.74(d)(2)(iv) and (d)(2)(v), based on additional clinical studies that supported effectiveness:

* * * Adults and children 2 to under 12 years of age: Add 1 tablespoonful of solution, for each quart of water, directly to the water in a hot steam vaporizer, bowl, or wash basin; or add 1½ teaspoonfuls of solution, for each pint of water, to an open container of boiling water. Breathe in the medicated vapors. May be repeated up to three times daily or as directed by a doctor. Children under 2 years of age: consult a doctor.

When the final monograph was published, the agency was not aware of safety problems occurring when products containing camphor and/or menthol are added to hot water. Since that time, the agency has received new information (Refs. 1, 2, and 3) that indicates that the current warnings and directions may not be adequate and that safety concerns (e.g., burns caused by flashing) could arise if these products are heated near an open flame, in a container of hot water, or in a microwave oven. From 1983 to mid-1997, 34 fire-related events from usage of antitussive drug products containing camphor and menthol were reported (Refs. 2 and 3). Twenty-one fire-related events concerned a combination of camphor and menthol in an ointment vehicle. This product when added to hot water in a container on the stove, or when added to water and heated in a microwave oven, caused flashing and severe burns. One of the 21 events involved adding the product to hot water in a vaporizer. An additional 11 events concerned heating products that were combinations of camphor and menthol in an alcohol-based solution. These products, like the products in the ointment vehicles, also caused flashing and burns when placed in hot water or